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10/524,553	10/11/2005	Yoram Palti	P-5061-US	9116

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EXAMINER	
ELHASSAN, AHMED A	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,553	PALTI, YORAM	
	Examiner	Art Unit	
	AHMED ELHASSAN	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 3 and 4 are objected to, because of the following informalities: inconsistent terminology when referring to the same element; the receptacle, containing the agglutinative particles, is referred to as both "chamber" and "sampling chamber". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 7, 9, 11, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 7 & 15, these are improper Markush-type claims due to use of the alternative in listing elements of the group to select from; a Markush-type claim recites alternatives in a format such as “selected from the group consisting of A, B and C.

Regarding claim 9, it is unclear how “change of color" is different from “change of hue” and how “change of brightness” is different from “change of intensity”. Therefore, the inclusion of redundant elements in the Markush group is improper.

Regarding claim 11, it is unclear which further structural limitations of the claimed system are set forth by specifying the “body lumen” as the “gastrointestinal tract”.

Regarding claim 14, this claim does not provide any further structural limitation to any of the claimed elements in parent claim .

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1- 5 and 7-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Cote et al. (US 6485703).

Regarding claim 1, Cote discloses a system (col. 15, line 16) for in vivo (col. 17, line 51) analysis, said system comprising agglutinative particles ("analyte binding component", col. 15, line 4) capable of interacting with at least one analyte so as to cause an optical change (col. 8, line 16); and at least one in vivo imaging system (CCD, col. 37, line 43) configured for detecting the optical change.

Regarding claim 2, Cote as applied to claim 1, includes an illumination source (col. 35, line 67).

Regarding claim 3, Cote as applied to claim 1, includes a chamber configured for containing the agglutinative particles and an in vivo sample (central body of hydrogel material, col. 10, line 24, molded in a particular shape, col. 10, line 30, on which agglutinative particles are attached, and directly exposed to the bodily-fluid where analyte to be detected is also present, col. 32, line 55)

Regarding claim 4, Cote as applied to claim 1, includes that sampling chamber is at least partially transparent (transparency inherent in CCD , col. 37, line 43, optical detection of color change, col. 8, line 32, upon interaction of attached agglutinative particles with detected analyte)

Regarding claim 5, Cote as applied to claim 3, includes that the imaging system is configured for imaging the chamber (inherent in the device CCD detection, col. 37, line 43, of optical change upon interaction of attached agglutinative particles with detected analyte).

Regarding claim 7, Cote as applied to claim 1, shows that agglutinative particles include antibodies (col. 8, line 4).

Regarding claim 8, Cote as applied to claim 3, includes that an analyte is in the in vivo sample (Abs. line, 1, line 8 & col. 9, lines 10-14).

Regarding claim 9, Cote as applied to claim 1, includes that the optical change is a change of color (col. 8, line 32).

Regarding claim 10, Cote as applied to claim, discloses that the in vivo imaging system includes a CCD (col. 37, line 43).

2. Claims 6, 11, and 12- 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cote as applied to claim1 above, and further in view of Iddan et al. (US 6428469).

The applied reference has a common inventor, Mr. Gavriel J. Iddan, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l) (1) and § 706.02(l) (2).

Regarding claim 6, Cote as applied to claim 1, lacks that the imaging system is configured for imaging a body lumen.

Iddan teaches an imaging system (FIG. 4) configured for imaging a body lumen ("GI tract", col. 1, line 62), for internal medical inspection of the GI tract.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Cote with an imaging system configured for imaging a body lumen, in view of

Iddan with the motivation of internal medical inspection of lumen where analyte is detected.

Regarding claim 11, Cote-Iddan as applied to claim 6, includes that the body lumen is the gastrointestinal tract (col. 1, line 62).

Regarding 12, Cote as applied to claim 1, lacks that a transmitter.

Iddan discloses a transmitter for communicating imaging data to an external station (FIG. 2, No. 27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Cote with transmitter, in view of Iddan with the motivation to communicate imaging data to an external station.

Regarding claim 13, Cote-Iddan as applied to claim 12, includes that the transmitter is configured for transmitting image data (FIG. 2, No. 27, col. 2, lines 64-65 & col. 1, lines 30-31 & 42-43).

Regarding claim 14, Cote-Iddan as applied to claim 12 includes a device for in-vivo analysis (Cote; col. 15, line 16)

Regarding claim 15, Cote-Iddan as applied to claim 14, includes that the device is selected from the group consisting of: needles, stents, endoscopes (Cote; "fiber optic for remote sensing internal body cavity", col. 32-34), catheters or ingestible capsules.

3. Claims 16, and 18 - 21 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Iddan in view of Cote.

Regarding claim 16, Iddan discloses an ingestible capsule (FIG. 4) comprising:

an optical window (No. 40, FIG. 4), at least one imaging system (No. 12, FIG. 4) configured for detecting at least the optical change; and

a transmitter (No 12, FIG. 1 & No. 27 FIG. 2) configured for transmitting image data to an external receiving system.

Iddan lacks that said window has immobilized thereto agglutinative particles capable of interacting with at least one analyte so as to cause an optical change;

Cote teaches a glass surface (col. 26, line 11) having immobilized thereto agglutinative particles capable of interacting with at least one analyte so as to cause an optical change (col. 8, line 16);

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Iddan window with a region having immobilized thereto agglutinative particles capable of interacting with at least one analyte so as to cause an optical change, in view of Cote, with the motivation to detect the presence of an analyte in a bodily fluid.

Regarding claim18 the method claimed is inherent to the operation of Iddan-Cote system as included in the rejection of claim 16, above;

Regarding claim 19, Iddan- Cote as applied to claim 18, shows that detecting the optical change includes imaging the combined sample (Cote; optical change being caused by combining of agglutinative particle and analyte to form combined sample in the first place ,col. 8, line 16).

Regarding claim 20, Iddan- Cote as applied to claim 19 includes obtaining images of the body lumen (Iddan; Abs. line, 1).

Regarding claim 21, Iddan- Cote as applied to claim 20 includes the step of transmitting data to an external receiving unit (Iddan, No 12, FIG. 1 & col. 1, lines 42-43).

4. Claims 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan

in view of Cote further in view of Minshull et al. (US 2002/0127623).

Regarding claim17, Iddan-Cote as applied to claim 16 lacks that the device includes a chamber configured for containing the agglutinative particles and an in-vivo sample.

Minshull teaches an in vivo ([0159, line 5) optical sensor ([0159], line 3) with a chamber ([0073, line 12) configured for containing the agglutinative particles and an in vivo sample in order to well-mix or the anayte and the agglutinative particles, or well incubate attached bio-particles and proteins or cells in the sample.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Iddan-Cote with a chamber configured for containing the agglutinative particles and the in-vivo sample, in view of Minshull, with the motivation to well-mix or the anayte and the agglutinative particles, or well incubate attached bio-particles and proteins or cells in the sample.

5. Claims 16, 18, 19, 20, 21 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Yokoi et al. (US 6,951,536) in view of Cote.

Regarding claim 16, Yokoi discloses an ingestible ("swallowing" col. 1, line 56), capsule (FIG. 24) comprising:

an optical window (No. 105a, FIG. 24), at least one imaging system (No. 107a, FIG. 24) configured for detecting at least the optical change; and

a transmitter (No 112a, FIG. 24) configured for transmitting image data to an external receiving system.

Yokoi lacks that said window has immobilized thereto agglutinative particles capable of interacting with at least one analyte so as to cause an optical change;

Cote teaches a glass surface (col. 26, line 11) having immobilized thereto agglutinative particles capable of interacting with at least one analyte so as to cause an optical change (col. 8, line 16);

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Yokoi window with having a region immobilized thereto agglutinative particles capable of interacting with at least one analyte so as to cause an optical change, in view of Cote, with the motivation to detect the presence of an analyte in a bodily fluid.

Regarding claim18 the method claimed is inherent to the operation of Yokoi - Cote system as included in the rejection of claim 16, above;

Obtaining a sample (Cote; analyte binds to attached agglutinative particles) from a body lumen (Yokoi; col. 16, line 11);
combining in vivo the sample with agglutinative particles; and
detecting at least one optical change in the combined sample (Cote; col. 8, line 16).

Regarding claim 19, Yokoi- Cote as applied to claim 18, shows that detecting the optical change includes imaging the combined sample (Cote; inherent in optical change being caused by combining of agglutinative particle and analyte to form combined sample in the first place ,col. 8, line 16).

Regarding claim 20, Yokoi- Cote as applied to claim 19 includes obtaining images of the body lumen (inherent in imaging system No. 107a, FIG. 24, and the ingestible capsule being inside a body cavity with lumen once swallowed).

Regarding claim 21, Yokoi- Cote as applied to claim 20 includes the step of transmitting data to an external receiving unit (No 112a, FIG. 24).

6. Claims 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi in view of Cote further in view of Minshull et al. (US 2002/0127623).

Regarding claim17, Yokoi -Cote as applied to claim 16 lacks that the device includes a chamber configured for containing the agglutinative particles and an in-vivo sample.

Minshull teaches an in vivo ([0159, line 5) optical sensor ([0159], line 3) with a chamber ([0073, line 12) configured for containing the agglutinative particles and an in vivo sample in order to well-mix or the anayte and the agglutinative particles, or well incubate attached bio-particles and proteins or cells in the sample.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Yokoi -Cote with a chamber configured for containing the agglutinative particles and the in-vivo sample, in view of Minshull, with the motivation to well-mix or the anayte and the agglutinative particles, or well incubate attached bio-particles and proteins or cells in the sample.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AHMED ELHASSAN whose telephone number is (571)270-7390. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

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Examiner, Art Unit 3768